510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091833 .

1. Submitter's Identifications:

Gemore Technology Co., Ltd.
11FL., NO. 29-5, Sec. 2, Chung Cheng E. RD.,
Tan Shui, Taipei Hsien, Taiwan

OCT 16 2009

Contact:
Mr.Boden S.P. Lai
President & Official Correspondent

Date of Summary Preparation: August 30,2009.

2. Name of the Device:

Trade name:	GEN-TONE Abdominal Training system; model GEM-TONE 310PE/320PE/330PE/340PE/350PE
Common name:	Powered Muscle Stimulator
Classification name:	Stimulator, Muscle, Powered
Product Code:	NGX

3. Information of the 510(k) Cleared Device (Predicate Device):

For this 510(k) submission, we compared our models to the following FDA cleared OTC devices:

- K010335: Slendertone Flex, made by Bio-Medical Research Ltd.

4. Device Description:

The GEM-TONE Abdominal Training System model GEM-TONE 310PE/ 320PE /330PE /340PE / 350PE is battery-operated programmable muscle stimulator intended to improve or facilitate muscle performance by applying an electrical current to electrodes, which is attached on abdomen region.

GEM-TONE Abdominal Training System model GEM-TONE 310PE / 320PE /330PE /340PE /350PE, consists mainly of three parts: the stimulator , electrodes, and support belts fitting for special parts of body. The stimulator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the specified region, so as to transmit this stimulus current to the region of abdomen for the following intended purposes:
- Strengthening, toning and firming of the abdomen region.

The GEMORE GEM-TONE Abdominal Training System and its stimulation programs are not designed for injured or ailing muscles, and use on such muscles is contraindication.

To adequately locate the stimulation on the intended treatment area, the following support belt is provided together with the stimulator:

- The abdomen belt, which is capable of connecting to the both two output channels of stimulator.

The stimulation mode for GEM-TONE Abdominal Training System includes several different operation modes as mentioned on the comparison table. These operation modes are generated from the software control by using the microprocessor as its main control unit.

5. Intended Use:

Basically the indication for use is defined clearly as the description of the following statement:

The GEMORE GEM-TONE Abdominal Training System/model GEM-TONE 310PE/320PE/330PE/340PE/350PE are the electrical muscle stimulator intended for the following indication for use:

- Strengthening, toning and firming of the abdomen region.

The GEMORE GEM-TONE Abdominal Training System and its stimulation programs are not designed for injured or ailing muscles, and use on such muscles is contraindication.

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.
In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

The GEM-TONE Abdominal Training System, model GEM-TONE 310PE / 320PE /330PE /340PE /350PE, has the same intended use and technological characteristics as the cleared device of Slendertone Flex (K010335) . Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted model could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Therefore, the GEM-TONE Abdominal Training System, model GEM-TONE 310PE / 320PE /330PE /340PE /350PE, is substantial equivalent to the chosen predicate model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Gemore Technology Co., Ltd.
% Mr. Boden Lai
11FL, No. 29-5, Sec. 2, Chung Cheng E. Road,
Tan Shui, Taipei Hsien
China (Taiwan) 251

OCT 16 2009

Re: K091833
Trade/Device Name: GEM-TONE Abdominal Training System, Models 310PE, 320PE, 330PE, 340PE, and 350PE
Regulation Name: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: September 5, 2009
Received: September 8, 2009

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: GEM-TONE Abdominal Training System / Model: GEM-TONE 310PE/320PE/330PE/340PE/350PE.

Indications For Use:

The GEMORE GEM-TONE Abdominal Training System/model GEM-TONE 310PE/320PE/330PE/340PE/350PE are the electrical muscle stimulator intended for the following indication for use:

- Strengthening, toning and firming of the abdomen region.

The GEMORE GEM-TONE Abdominal Training System and its stimulation programs are not designed for injured or ailing muscles, and use on such muscles is contraindication.

Prescription Use _____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091833